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File: DWPI

Aug 9, 2001

DERWENT-ACC-NO: 2001-465701

DERWENT-WEEK: 200150

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TITLE: A transfer factor (I) effective to confer cell-mediated immunity to Human Herpesvirus-6A (HHV-6A) and Human Herpesvirus-6B and for treating chronic fatigue syndrome and multiple sclerosis

INVENTOR: SHULER, R R; WILSON, G B ; BREWER, J H

PRIORITY-DATA: 2000US-179647P (February 2, 2000), 2001US-0776010 (February 2, 2001)

## PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
WO 200156608 A1	August 9, 2001	E	024	A61K045/05
US 2001033844 A1	October 25, 2001		000	A61K039/245
AU 200136636 A	August 14, 2001		000	A61K039/245

INT-CL (IPC): A61  $\times$  39/00; A61  $\times$  39/245; A61  $\times$  45/05; C12 Q 1/70

ABSTRACTED-PUB-NO: US2001033844A

**BASIC-ABSTRACT:** 

NOVELTY - A transfer factor (I) effective to confer cell-mediated immunity where the immune response is to Human Herpesvirus-6A (HHV-6A) and Human Herpesvirus-6B (HHV-6B), is new.

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for the following:

- (1) Producing (M1) (I) comprising immunizing a lactating animal with HHV-6A and HHV-6B, recovering the colostrum from the animal and preparing (I) from the colostrum or immunizing an animal with HHV-6A and HHV-6B, recovering the immune system component from the animal and preparing (I) from the component;
- (2) Producing (M2) a composition comprising producing (I) and admixing a carrier.

ACTIVITY - Immunostimulant; neuroprotective; antiviral; analeptic.

MECHANISM OF ACTION - Cell-mediated-immunity-stimulator; vaccine.

Colostrum samples from bovines immunized with HHV-6A and HHV-6B antigens were used as the source for preparation of TF (I). The TF was administered orally. A placebo controlled double blind experiment was performed consisting of 2 patient groups. Group I (HHV-6 TF group) consisted of chronic fatigue syndrome and multiple sclerosis patients who received capsules containing the HHV-6A and HHV-6B TF. Group II (Placebo TF Group) consisted of patients who received control TF preparation. Both groups were evaluated over a period of four months. All patients received 2 capsules three times a day during day 1 to 5, day 31 to 35, and day 61 to 65 of the study. 5 of 8 chronic fatigue syndrome patients who received the HHV-6 TF had a 50% greater reduction in their score and 5 of 8 showed an increase of 50% or greater in their NK cells. Zero controls showed a decrease in symptoms by 50% or an increase in NK cell function by

50%.

USE - (I) is useful for treating chronic fatigue syndrome, multiple sclerosis, an abnormality alleviated by enhancing a subjects immune response to HHV-6A and/or HHV-6B (all claimed).

ABSTRACTED-PUB-NO:

WO 200156608A EQUIVALENT-ABSTRACTS:

ABSTRACTED-PUB-NO: US2001033844A

NOVELTY - A transfer factor (I) effective to confer cell-mediated immunity where the immune response is to Human Herpesvirus-6A (HHV-6A) and Human Herpesvirus-6B (HHV-6B), is new.

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for the following:

- (1) Producing (M1) (I) comprising immunizing a lactating animal with HHV-6A and HHV-6B, recovering the colostrum from the animal and preparing (I) from the colostrum or immunizing an animal with HHV-6A and HHV-6B, recovering the immune system component from the animal and preparing (I) from the component;
- (2) Producing (M2) a composition comprising producing (I) and admixing a carrier.

ACTIVITY - Immunostimulant; neuroprotective; antiviral; analeptic.

MECHANISM OF ACTION - Cell-mediated-immunity-stimulator; vaccine.

Colostrum samples from bovines immunized with HHV-6A and HHV-6B antigens were used as the source for preparation of TF (I). The TF was administered orally. A placebo controlled double blind experiment was performed consisting of 2 patient groups. Group I (HHV-6 TF group) consisted of chronic fatigue syndrome and multiple sclerosis patients who received capsules containing the HHV-6A and HHV-6B TF. Group II (Placebo TF Group) consisted of patients who received control TF preparation. Both groups were evaluated over a period of four months. All patients received 2 capsules three times a day during day 1 to 5, day 31 to 35, and day 61 to 65 of the study. 5 of 8 chronic fatigue syndrome patients who received the HHV-6 TF had a 50% greater reduction in their score and 5 of 8 showed an increase of 50% or greater in their NK cells. Zero controls showed a decrease in symptoms by 50% or an increase in NK cell function by 50%.

USE - (I) is useful for treating chronic fatigue syndrome, multiple sclerosis, an abnormality alleviated by enhancing a subjects immune response to HHV-6A and/or HHV-6B (all claimed).

EQUIVALENT-ABSTRACTS: NOVELTY - A transfer factor (I) effective to confer cell-mediated immunity where the immune response is to Human Herpesvirus-6A (HHV-6A) and Human Herpesvirus-6B (HHV-6B), is new. DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for the following: (1) Producing (M1) (I) comprising immunizing a lactating animal with HHV-6A and HHV-6B, recovering the colostrum from the animal and preparing (I) from the colostrum or immunizing an animal with HHV-6A and HHV-6B, recovering the immune system component from the animal and preparing (I) from the component; (2) Producing (M2) a composition comprising producing (I) and admixing a carrier. ACTIVITY - Immunostimulant; neuroprotective; antiviral; analeptic. MECHANISM OF ACTION - Cell-mediated-immunity-stimulator; vaccine. Colostrum samples from bovines immunized with HHV-6A and HHV-6B antigens were used as the source for preparation of TF (I). The TF was administered orally. A placebo controlled double blind experiment was performed consisting of 2 patient groups. Group I (HHV-6 TF group) consisted of chronic fatigue syndrome and multiple sclerosis patients who received capsules containing the HHV-6A and HHV-6B TF. Group II (Placebo TF Group) consisted of patients who received control TF preparation. Both groups were evaluated over a period of four

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to 35, and day 61 to 65 of the study. 5 of 8 chronic fatigue syndrome patients who received the HHV-6 TF had a 50% greater reduction in their score and 5 of 8 showed an increase of 50% or greater in their NK cells. Zero controls showed a decrease in symptoms by 50% or an increase in NK cell function by 50%. USE - (I) is useful for treating chronic fatigue syndrome, multiple sclerosis, an abnormality alleviated by enhancing a subjects immune response to HHV-6A and/or HHV-6B (all claimed). WO 200156608A

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=> "transfer factor"

L1 3880 "TRANSFER FACTOR"

=> "herpesvirus-6A"

L2 39 "HERPESVIRUS-6A"

=> L1 and L2

L3 1 L1 AND L2

=> "multiple sclerosis"

L4 28612 "MULTIPLE SCLEROSIS"

=> L4 and L1

L5 29 L4 AND L1

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=> herpesvirus and L5
            1 HERPESVIRUS AND L5
1.6
=> "chronic fatigue" and L1
           12 "CHRONIC FATIGUE" AND L1
=> herpesvirus and L7
            3 HERPESVIRUS AND L7
L8
=> D L8 IBIB TI SO AU ABS 1-3
    ANSWER 1 OF 3 CAPLUS COPYRIGHT 2002 ACS
                        2001:581739 CAPLUS
ACCESSION NUMBER:
                        135:136432
DOCUMENT NUMBER:
                        Human herpes virus 6A and 6B transfer
TITLE:
                         factors for the treatment of chronic
                         fatigue syndrome and multiple sclerosis
                        Wilson, Gregory B.; Brewer, Joseph H.
INVENTOR(S):
                        Animune Inc., USA
PATENT ASSIGNEE(S):
                         PCT Int. Appl., 24 pp.
SOURCE:
                         CODEN: PIXXD2
DOCUMENT TYPE:
                         Patent
                         English
LANGUAGE:
FAMILY ACC. NUM. COUNT:
PATENT INFORMATION:
                                         APPLICATION NO. DATE
                  KIND DATE
     PATENT NO.
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                                         WO 2001-US3511 20010202
     WO 2001056608 A1 20010809
         W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN,
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             ZA, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM
         RW: GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW, AT, BE, CH, CY,
             DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR, BF,
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                                          US 2001-776010 20010202
                      A1 20011025
     US 2001033844
                                       US 2000-179647P P 20000202
PRIORITY APPLN. INFO.:
     Human herpes virus 6A and 6B transfer factors for the
     treatment of chronic fatigue syndrome and multiple
     sclerosis
SO
     PCT Int. Appl., 24 pp.
     CODEN: PIXXD2
     Wilson, Gregory B.; Brewer, Joseph H.
IN
     The present invention provides transfer factors that
AB
     confer cell-mediated immunity to Human Herpesvirus-6A and Human
     Herpesvirus-6B. The invention also provides pharmaceutical
     compns. comprising the transfer factors and methods of
     treating abnormalities in a subject using the transfer
     factors.
                               THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS
REFERENCE COUNT:
                         6
                               RECORD. ALL CITATIONS AVAILABLE IN THE RE
FORMAT
     ANSWER 2 OF 3 CAPLUS COPYRIGHT 2002 ACS
                    1997:42178 CAPLUS
ACCESSION NUMBER:
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126:102987

DOCUMENT NUMBER:

Lessons from a pilot study of transfer TITLE:

factor in chronic fatigue

syndrome

De Vinci, Caterina; Levine, Paul H.; Pizza, AUTHOR (S):

Giancarlo;

Fudenberg, Hugh H.; Orens, Perry; Pearson, Gary;

Viza,

SOURCE:

Dimitri

Immunoldiagnosis Immunotherapy Unit, 1st Div. Urology CORPORATE SOURCE:

Sant'Orsola-Malpighi Hosp., Bologna, Italy Biotherapy (Dordrecht, Neth.) (1996), 9(1/3, Biological Response Modifiers in Research and

Treatment of Cancer, Infectious Diseases, and Immunological and Inflammatory Disorders), 87-90

CODEN: BTHREW; ISSN: 0921-299X

Kluwer PUBLISHER: DOCUMENT TYPE: Journal English LANGUAGE:

Lessons from a pilot study of transfer factor in

chronic fatigue syndrome

Biotherapy (Dordrecht, Neth.) (1996), 9(1/3, Biological Response

Modifiers

in Research and Treatment of Cancer, Infectious Diseases, and

Immunological and Inflammatory Disorders), 87-90

CODEN: BTHREW; ISSN: 0921-299X

De Vinci, Caterina; Levine, Paul H.; Pizza, Giancarlo; Fudenberg, Hugh ΑU

Н.;

Orens, Perry; Pearson, Gary; Viza, Dimitri

Transfer Factor (TF) was used in a placebo controlled AB pilot study of 20 patients with chronic fatigue syndrome (CFS). Efficacy of the treatment was evaluated by clin. monitoring and testing for antibodies to Epstein-Barr virus (EBV) and human herpes virus-6 (HHV-6). Of the 20 patients in the placebo-controlled trial, improvement was obsd. in 12 patients, generally within 3-6 wk of beginning treatment. Herpes virus serol. seldom

correlated with clin. response. This study provided experience with oral

TF, useful in designing a larger placebo-controlled clin. trial.

ANSWER 3 OF 3 CAPLUS COPYRIGHT 2002 ACS 1997:42172 CAPLUS ACCESSION NUMBER:

126:88153 DOCUMENT NUMBER:

Use of anti HHV-6 transfer factor TITLE:

for the treatment of two patients with chronic

fatigue syndrome (CFS). Two case reports

Ablashi, Dharam V.; Levine, Paul H.; De Vinci, AUTHOR(S):

Caterina; Whitman, James E., Jr.; Pizza, Giancarlo;

Viza, Dimitri

Advanced Biotechnologies Inc., Columbia, MD, 21046, CORPORATE SOURCE:

USA

Biotherapy (Dordrecht, Neth.) (1996), 9(1/3, SOURCE:

Biological Response Modifiers in Research and Treatment of Cancer, Infectious Diseases, and Immunological and Inflammatory Disorders), 81-86

CODEN: BTHREW; ISSN: 0921-299X

Kluwer PUBLISHER: Journal DOCUMENT TYPE: English LANGUAGE:

Use of anti HHV-6 transfer factor for the treatment of two patients with chronic fatigue syndrome (CFS). Two

case reports

SO Biotherapy (Dordrecht, Neth.) (1996), 9(1/3, Biological Response Modifiers

in Research and Treatment of Cancer, Infectious Diseases, and Immunological and Inflammatory Disorders), 81-86
CODEN: BTHREW; ISSN: 0921-299X

- AU Ablashi, Dharam V.; Levine, Paul H.; De Vinci, Caterina; Whitman, James E., Jr.; Pizza, Giancarlo; Viza, Dimitri
- AB Specific human herpes virus-6 (HHV-6) transfer factor
  (PF) prepn., administered to 2 chronic fatigue
  syndrome patients, inhibited the HHV-6 infection. Prior to treatment,
  both patients exhibited an activated HHV-6 infection. TF treatment
  improved the clin. manifestations of CFS in one patient who resumed
  normal

duties within weeks, whereas no clin. improvement was obsd. in the second patient. Thus, HHV-6 specific TF may be of value in controlling HHV-6 infection and related illnesses.

## => D L3 TI SO AU ABS

- L3 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2002 ACS
- TI Human herpes virus 6A and 6B transfer factors for the treatment of chronic fatigue syndrome and multiple sclerosis
- SO PCT Int. Appl., 24 pp. CODEN: PIXXD2
- IN Wilson, Gregory B.; Brewer, Joseph H.
- The present invention provides transfer factors that confer cell-mediated immunity to Human Herpesvirus-6A and Human Herpesvirus-6B. The invention also provides pharmaceutical compns. comprising the transfer factors and methods of treating abnormalities in a subject using the transfer factors.

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<u>L14</u>	herpesvirus	3151	<u>L14</u>
<u>L13</u>	L8 and perpesvirus	0	<u>L13</u>
<u>L12</u>	L11	0	<u>L12</u>
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<u>L9</u>	HHV-6 and L8	0	<u>L9</u>
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<u>L7</u>	animune	1	<u>L7</u>
<u>L6</u>	animune inc.	0	<u>L6</u>
<u>L5</u>	Brewer J.in.	0	<u>L5</u>
<u>L4</u>	Brewer JH.in.	0	<u>L4</u>
<u>L3</u>	L2 and transfer adj factor	2	<u>L3</u>
<u>L2</u>	Wilson G.in.	168	<u>L2</u>
<u>L1</u>	Wilson GB.in.	0	<u>L1</u>

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Entrez					Related Articles
PubMed	1: Wilson GB, Poindexte	r C, Fort JD, Ludd	en KD.		
	De novo initiation o	f specific cell-r	nediated immur	ne responsivenes	s in chickens by
,	transfer factor (spec	ific immunity if	nducer) obtaine	a mom bovine co	Jiosti and
	milk. Acta Virol. 1988 Jan;32	(1):6-18.			
PubMed	PMID: 2897772 [PubM	led - indexed for M	(EDLINE)		
Services		•			Related Articles
	<b>2:</b> Vasily DB, Miller OF,	Fudenberg HH, C	Soust JM, Wilson C	<u>iB.</u>	
	Epidermodysplasia	verruciformis:	response to ther	rapy with dialyza	ible leukocyte
	extract (transfer fac J Clin Lab Immunol. 19	tor) derived fro 184 May:14(1):49-	m nouselloid co 57	omacis.	
	PMID: 6086930 [PubM	led - indexed for N	MEDLINE]		
					Related Articles
·	3: Wilson GB, Fudenber	g HH, Keller RH.		1 . C	
	Guidelines for imm	unotherapy of a	antigen-specific	defects with tha	iisici iactoi.
Related	J Clin Lab Immunol. 19 PMID: 6202873 [PubM	1ed - indexed for N	MEDLINE]		
Resources	1 1/125. 0202075 [= 0.00				
	4: Wilson GB, Metcalf J	F, Fudenberg HH.			Related Articles
	Treatment of Myco	bacterium fortu	itum pulmonar	y infection with	"transfer factor"
	(TF): new methodo	logy for evalua	ting TF potency	and predicting	clinical response.
	Clin Immunol Immuno PMID: 7049471 [PubN	pathol. 1982 May; Med - indexed for I	MEDLINE]	aostract available.	
	1 14115. 70 15 17 [2 465]		-		<b>-</b>
	5: Wilson GB, Paddock	GV, Fudenberg H	<u>H.</u>		Related Articles
	Bovine 'transfer fac	ctor': an oligoril	oonucleopeptide	e which initiates	antigen-specific
	lymphocytes respon	nsiveness.			
	Thymus. 1982;4(6):33 PMID: 6191411 [Publ	5-50. Med - indexed for :	MEDLINE]		
	TIMID. 0151111 [1 do.	,	-		
	6: Wilson GB, Paddock	GV, Fudenberg H	<u>н.</u>		Related Articles
	Effects of dialyzab	le leukocyte ex	tracts with trans	sfer factor activi	ty on leukocyte
	migration in vitro.	V. Antigen-spe	ecific lymphocy	te responsivenes	s can be initiated
	by two structurally Thymus. 1981 Feb;2(4	distinct polyrit	onucleopephae	<b>28.</b>	
	PMID: 6165106 [Publ	Med - indexed for	MEDLINE]		
					Related Articles
	7: Fudenberg HH, Wils	on GB, Smith CL.		. 1 . 1 . 6	
	Immunotherapy w	ith dialyzable le	eukocyte extract	ts and studies of	tneir
	antigen-specific (tr	ranster tactor) a	ictivity.		

Proc Virchow Pirquet Med Soc. 1980 Dec;34:3-87. Review. No abstract available. PMID: 6270691 [PubMed - indexed for MEDLINE] 8: Kyong CU, Wilson GB, Fudenberg HH, Goust JM, Richardson P, Echerd J. Related Articles Chorioretinitis with a combined defect in T and B lymphocytes and granulocytes. A new syndrome successfully treated with dialyzable leukocyte extracts (transfer factor). Am J Med. 1980 Jun;68(6):955-61. PMID: 6992573 [PubMed - indexed for MEDLINE] Related Articles 9: Wilson GB, Fudenberg HH, Jonsson HT Jr, Smith CL. Effects of dialyzable leukocyte extracts (DLE) with transfer factor activity on leukocyte migration in vitro. IV. Two distinct effects of DLE on leukocyte migration can be produced by prostaglandins. Clin Immunol Immunopathol. 1980 May;16(1):90-102. No abstract available. PMID: 7379353 [PubMed - indexed for MEDLINE] Related Articles 10: Wilson GB, Newell RT, Burdash NM. Bovine dialyzable lymph node extracts have antigen-dependent and antigen-independent effects on human cell-mediated immunity in vitro. Cell Immunol. 1979 Sep 15;47(1):1-18. No abstract available. PMID: 315822 [PubMed - indexed for MEDLINE] **Related Articles** 11: Wilson GB, Smith CL, Fudenberg HH. Effects of dialyzable leukocyte extracts (DLEs) with transfer factor activity on leukocyte migration in vitro. III. Characterization of the antigen-independent migration inhibition factor in DLEs as a neutrophil immobilizing factor. J Allergy Clin Immunol. 1979 Jul;64(1):56-66. PMID: 447952 [PubMed - indexed for MEDLINE] **Related Articles** 12: Wilson GB, Fudenberg HH. Effects of dialyzable leukocyte extracts with transfer factor activity on leukocyte migration in vitro. II. Separation and partial characterization of the components in DLE producing antigen-dependent and antigen-independent effects. J Lab Clin Med. 1979 May;93(5):819-37. PMID: 429877 [PubMed - indexed for MEDLINE] Related Articles 13: Wilson GB, Fudenberg HH, Horsmanheimo M. Effects of dialyzable leukocyte extracts with transfer factor activity on leukocyte migration in vitro. 1. Antigen-dependent inhibition and antigen-independent inhibition and enhancement of migration. J Lab Clin Med. 1979 May;93(5):800-18. PMID: 429876 [PubMed - indexed for MEDLINE] **Related Articles** 14: Wilson GB, Fudenberg HH, Paddock GV. Detection of "dialyzable transfer factor" in vitro: structural and chemical characterization of the activity specific for tuberculin. Ann N Y Acad Sci. 1979;332:579-90. No abstract available. PMID: 294834 [PubMed - indexed for MEDLINE] Related Articles 15: Wilson GB, Paddock GV, Fudenberg HH. The chemical nature of the antigen-specific moiety of transfer factor.

Trans Assoc Am Physicians. 1979;92:239-56. No abstract available. PMID: 95068 [PubMed - indexed for MEDLINE]

16: Wilson GB, Fudenberg HH, Bahm VJ.

Related Articles

Distinct components in dialyzable leukocyte extracts (DLE) have specific and nonspecific effects on cellular immunity as shown by leukocyte migration inhibition. Trans Assoc Am Physicians. 1978;91:295-332. No abstract available.

PMID: 754397 [PubMed - indexed for MEDLINE]

17: Wilson GB, Welch TM, Knapp DR, Horsmanheimo A, Fudenberg HH.

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Characterization of Tx, an active subfraction of human dialyzable transfer factor. I. Identification of the major component in TFg, a precursor of Tx, as hypoxanthine. Clin Immunol Immunopathol. 1977 Nov;8(3):551-68. No abstract available.

PMID: 912950 [PubMed - indexed for MEDLINE]

18: Wilson GB, Welch TM, Fudenberg HH.

Related Articles

Tx: a component in human dialyzable transfer factor that induces cutaneous delayed hypersensitivity in guinea pigs.

Clin Immunol Immunopathol. 1977 Mar;7(2):187-202. No abstract available.

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